

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR REGENERATIVE  
MEDICINE, and STEM CELL & REGENERATIVE  
MEDICINE INTERNATIONAL, INC.,

Plaintiffs and Counterclaim-Defendants,

v.

IMSTEM BIOTECHNOLOGY, INC., XIAOFANG  
WANG, and REN-HE XU,

Defendants and Counterclaim-Plaintiffs.

C.A. NO. 1:17-cv-12239-ADB

**Leave to File Under Seal Granted on  
September 11, 2019 (Dkt. No. 94)**

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF ITS  
MOTION FOR LEAVE TO FILE AN AMENDED COMPLAINT**

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## **I. INTRODUCTION**

Plaintiffs Astellas Institute for Regenerative Medicine and Stem Cell & Regenerative Medicine International, Inc. (collectively “Astellas”) respectfully ask the Court to add a new count in an Amended Complaint for breach of contract, for violations of confidentiality and use agreements. Astellas’ proposed Amended Complaint is attached as Exs. A (clean) and B (redline) to Plaintiffs’ Motion to Amend. The new breach of contract claim arises out of ImStem Biotechnology, Inc., Xiaofang Wang, and Ren-He Xu’s (collectively “Defendants”) new theory of time-barred defenses and is supported by recent discovery. The claim is grounded in the same facts and circumstances that have already been litigated in this case. Because this count arises from the same underlying transactions and facts as the pending matter, it is in the best interest of judicial efficiency to resolve all these disputes in one litigation. No new discovery or change in schedule will result by the addition of this claim.

## **II. STATEMENT OF RELEVANT FACTS**

### **A. Case Status**

On November 13, 2017, Astellas brought this action against Defendants to correct the inventorship of U.S. Patent No. 9,745,551 (“the ’551 patent”) and to assert state law claims arising from Defendants’ wrongful use and patenting of Astellas’ groundbreaking stem cell technology. Astellas employees, Drs. Erin Kimbrel and Robert Lanza invented a novel method for generating a specialized type of stem cell called a mesenchymal stem cell (“MSC”). (Dkt. 1 at ¶ 3.) Despite agreeing to keep Astellas’ proprietary protocols and cells confidential and only to use them to run agreed-upon experiments, Defendants took Astellas’ innovative technology and filed a patent application claiming it as their own. Further, Defendants Wang and Xu formed a company to exploit Astellas’ technology, leveraging this technology to seek funding for their company.

Defendants Xiaofang Wang and ImStem Biotechnology Inc. (“ImStem”) counterclaimed seeking to add Dr. Wang as an inventor to Astellas’ United States Patent No. 8,961,956 (“’956 patent”). (Dkt.

20.) Defendant Xu answered the complaint separately, on June 8, 2018, without asserting any counterclaims. (Dkt. 33.)

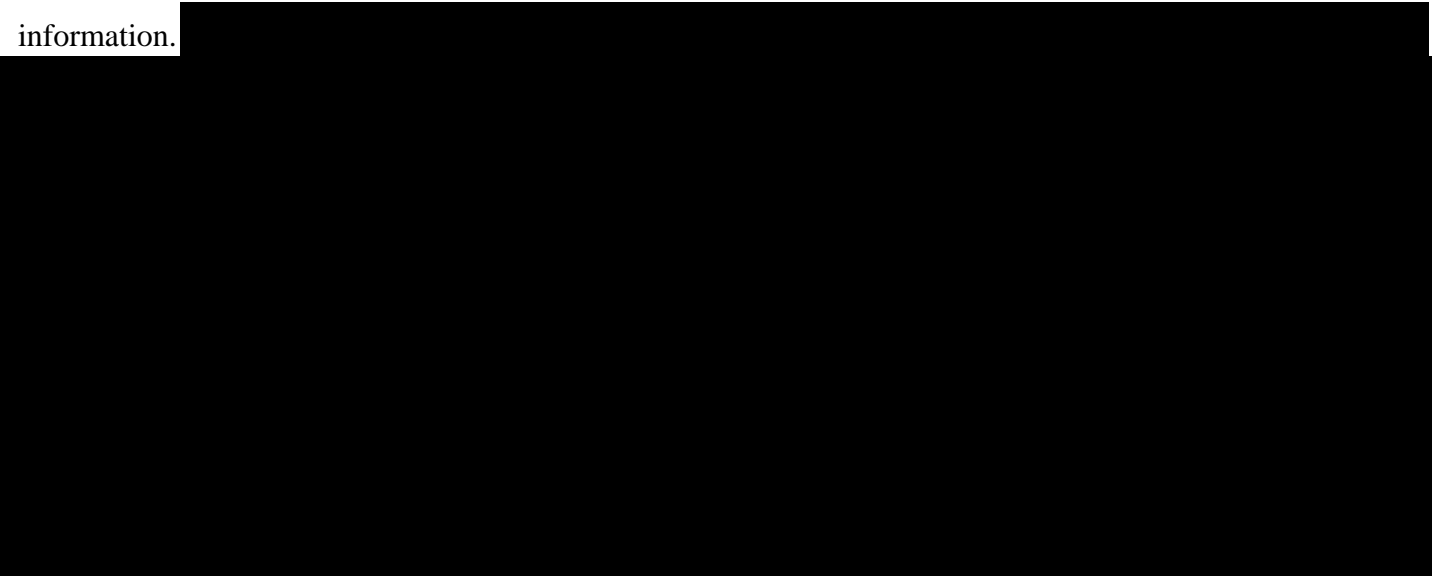
The Court issued its scheduling order on October 16, 2018, requiring all motions to amend pleadings be served by October 29, 2018. (Dkt. 44.) On July 22, 2019, Defendants moved for leave to amend their Answer and Counterclaims to add, *inter alia*, a counterclaim of correction of inventorship to add Defendants Wang and Xu as inventors to another Astellas' patent, U.S. Patent No. 8,962,321 ("321 patent") and a statute of limitations defense to Astellas' state law claims. (Dkt. 71.) On August 21, 2019, the Court granted Defendants' motion in part to add this counterclaim and affirmative defense. (Dkt. 85.) Defendants filed their Amended Answer and Counterclaim eight days later, on August 29, 2019. (Dkt. 91.) In light of these amendments, the parties are working to finish additional discovery including another deposition of Dr. Xu, and are negotiating a schedule for expert discovery, summary judgment, and pre-trial submissions, with a goal of a late April 2020 trial. The parties have tentatively agreed to exchange opening expert reports on October 4, 2019.

#### **B. Facts Pertaining to Defendants' Breach of Contract of Confidentiality**

As the Court is familiar with the facts of this case based on recent filings, this motion will not rehash the background of this dispute. The proposed breach of contract claim arises out of specific written email communications made during the collaboration between Astellas and Defendants concerning Astellas' novel MSCs, made from human embryonic stem cells via a hemangioblast intermediate ("HB-MSCs"). (Dkt 1 at ¶¶2, 4-6.) Astellas asked Defendants to perform limited testing using Astellas' proprietary HB-MSCs. (*Id.* at ¶¶4, 5.) Defendants instead took the protocols, cells, methods, materials, and know-how that Astellas confidentially shared with them and, unbeknownst to Astellas, recruited investors, started their own company, and filed patent applications on these novel HB-MSCs. (*Id.* at ¶7.)

From the beginning, Astellas' scientists told Defendants that the HB-MSC technology, cells, and protocol were confidential. Scientists at Astellas (then just a small biotech company) also told Defendants

that they were filing patent applications on their proprietary cells and that such intellectual property was essential to their viability as a growing company. In response to Astellas' requests to maintain confidentiality of its materials, Defendants repeatedly assured Astellas that they would not disclose the information.



Most specifically, on December 7, 2011, Dr. Kimbrel stated that before the collaboration could move forward any further the parties needed to agree on terms. She set forth a detailed set of conditions that would have to be met and followed by Drs. Wang and Xu. Among those conditions, she expressly stated that "Detailed, proprietary protocols, cells, and preliminary data offered by ACT must be kept in the strictest of confidence" and that "[c]ollaborators are NOT to share any cells or protocols with third parties without the explicit written consent of ACT." (Ex. 3 to Sharkey Declaration, IMSTEM-0004606.) On December 9, 2011, Dr. Xu agreed on behalf of he and Dr. Wang, stating "I don't think I have any problem with these." *Id.*

Despite these assurances, less than nine months later Defendants breached their promise by incorporating Astellas' detailed methods for making HB-MSCs into a provisional patent application, which they disclosed to third parties—namely the United States Patent Office and ImStem's investors. At the same time, Defendants plotted ways to use this technology to financially benefit themselves. Indeed,

Defendants characterized their own patent application as an [REDACTED] (Ex. 4 to Sharkey Declaration, IMSTEM-0027835) they could utilize [REDACTED] [REDACTED] (Ex. 5 to Sharkey Declaration, IMSTEM-0031515). Further breaches included Defendants' failure to abide by the requirement that all intended uses of the HB-MSC cells needed to be agreed upon by Astellas. To the contrary, Defendants continued secretly testing and using their "modified" versions of Plaintiffs' protocols, which they then incorporated in the non-provisional patent application that became the '551 patent. Because of this breach of contract, Astellas was financially harmed, such as by the loss of the rights to any patents based on Plaintiffs' mesenchymal stem cell intellectual property and proprietary information, the loss of value to Astellas' intellectual portfolio, and the loss of time and expenses spent on the deceptive collaboration. (Ex. 6 to Sharkey Declaration, Cassidy Depo. Ex. 2.)

### III. LEGAL STANDARDS

As set forth in the Court's Order on Defendants' Motion to Amend (Dkt. 85), under Federal Rule of Civil Procedure 15(a), a party may amend a pleading more than 21 days after a motion to dismiss or answer has been filed only "with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). The "purpose of Rule 15 'is to provide maximum opportunity for each claim to be decided on its merits rather than on procedural technicalities.'" *McGowen v. Four Directions Dev. Corp.*, No. 1:12-CV-00109-JAW, 2013 WL 2455977, at \*6 (D. Me. June 6, 2013) (internal citations omitted). Where, as here, the motion to amend is filed after the deadline for amendment set forth in the scheduling order, Rule 16(b)'s good cause standard applies. *U.S. ex rel. D'Agostino v. EV3, Inc.*, 802 F.3d 188, 192 (1st Cir. 2015). "Rule 16(b)'s 'good cause' standard emphasizes the diligence of the party seeking the amendment." *O'Connell v. Hyatt Hotels*, 357 F.3d 152, 155 (1st Cir. 2004). Under this inquiry, "[p]rejudice to the opposing party remains relevant but is not the dominant criterion." *Id.*

An amendment may be barred if it would be futile, but "if leave to amend is sought before discovery is complete and neither party has moved for summary judgment, the accuracy of the 'futility'

label is gauged by reference to the liberal criteria of Federal Rule of Civil Procedure 12(b)(6).” *Hatch v. Dep’t for Children, Youth & Their Families*, 274 F.3d 12, 19 (1st Cir. 2001). Under this standard, an amendment will not be deemed futile unless it fails to support a “plausible entitlement to relief.” *Rodriguez-Ortiz v. Margo Caribe, Inc.*, 490 F.3d 92, 95 (1st Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007)).

#### **IV. ARGUMENT**

##### **A. There is Good Cause to Allow Amendment to Include Breach of Contract**

Good cause exists to allow Astellas leave to amend its complaint to include a breach of contract claim. As evidenced by Astellas’ proposed Amended Complaint (attached as Exs. A (clean) and B (redline) to Plaintiffs’ Motion to Amend), the breach of contract claim arises out of the same work that underlies all of the claims at issue on either side of the case. The breach of contract is based on written agreements by Defendants to not misuse, misappropriate, or otherwise disclose the proprietary HB-MSC technology that belongs to Astellas. Defendants broke that promise, filed a patent on the technology with the intent to harm Astellas in using its own technology, and immediately tried to commercialize the technology for themselves.

Throughout this case, Astellas has alleged tort claims for the misuse, misappropriation, and theft of its intellectual property. Astellas brought these claims within months of the issuance of the ’551 patent, as the cause of action for correction of inventorship does not accrue until a patent actually issues. Yet, nearly a year and a half into the dispute, Defendants, citing the need for “case development” and document review, suggested for the first time that they would seek to shield their nefarious conduct by raising a statute of limitations defense. (*See* Dkt. 71 at 11.) Similarly, Astellas, too, needed to review the documents Defendants produced, depose Defendants Wang and Xu, and consider admissions that Defendants made in their briefing on their motion for leave to amend before fully appreciating the most appropriate way to plead claims for relief, and in particular to rely on breach of a written contract.

Defendants’ committed a continuing program of deception and misconduct, relief for which appeared appropriately captured by the state law tort claims pled in the original complaint. Only after Defendants’ raised their statute of limitations defense did Plaintiffs diligently reanalyze the evidence to identify an action with a longer limitations period.

Equity is also a factor. Defendants’ statute of limitations defense is a belated, formalistic attempt to shield its theft and misuse of Astellas’ innovative technology. And, because Defendants did not raise this statute of limitations defense earlier in the case, Astellas had no cause to seek to add a separate breach of contract claim. Now that Defendants have been permitted to amend their affirmative defenses to add the statute of limitation defense—and, indeed, sought such amendment in a “disingenuous” and “sneaky” manner (*see* Dkt. 88, July 23, 2019 Hr’g Tr. at 11:23–12:8)—Astellas should be permitted to likewise amend its complaint to assert a cause of action based on facts long known to Defendants. *See e.g. Ivymedia Corp. v. Ilikebus, Inc.*, 233 F. Supp. 3d 228, 231 (D. Mass. 2017) (“defendants will not be prejudiced if the amendment is allowed [as] Defendants’ counsel have long been aware of the copyrights at issue”).

There is no undue delay, dilatory motive, or bad faith on Astellas’ part in bringing this claim. While the underlying communications giving rise to the contract claims were part of Astellas’ original complaint, Astellas developed information supporting its claim through discovery. *See e.g. Gouin v. Nolan Assocs., LLC*, 325 F.R.D. 521, 523 (D. Mass. 2017) (finding good cause where “defendant did not receive confirmation that plaintiff had such a ticket in her possession until her deposition in March 29, 2017” despite the fact that Defendant produced pertinent ticket information years earlier.) Astellas deposed Dr. Xu on this agreement on July 3, 2019, during which he confirmed that he understood the emails to be memorializing a confidentiality agreement between the parties. [REDACTED]



[REDACTED]

(citing (Ex. 3 to Sharkey Declaration, IMSTEM-004606.)<sup>1</sup>))

Further, there is no undue prejudice to Defendants in adding this claim as the operative facts have already been the subject of fact discovery. The parties already produced the relevant documents (*i.e.*, the emails setting forth the agreement) and elicited the pertinent testimony from each of the inventor witnesses regarding their understanding of what was confidential in this collaboration. *See* (Ex. 8 to Sharkey Declaration, Wang Dep. Tr., 97:22-98:1 [REDACTED])

[REDACTED] Likewise, both parties' 30(b)(6) witnesses have testified regarding the benefits and harms caused by this collaboration and the resulting dispute. There is simply no need for additional discovery or other change in any of the court's deadlines that would result from adding this breach of contract claim. Because Astellas' amendment is grounded in the same facts and circumstances already pled, allowing it to be heard is consistent with the overall goal of the Federal Rules to promote justice and discourage formalistic pleading requirements. *See Foman v. Davis*, 371 US 178, 181-82 (1962).

**B. The Breach of Contract Amendment is Not Futile**

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<sup>1</sup> It was difficult both before and even at Dr. Xu's deposition to elicit pertinent information as Dr. Xu was less than forthcoming regarding the incorporation of Astellas data into the ImStem patents, and frequently stonewalled when questioned about the patent filings. *See* (Ex. 7 to Sharkey Declaration, Xu Tr. at 156:1-157:21; 190:5-192:19; 208:8-212:7) [REDACTED]

Astellas' amendment is not futile as the breach of contract claim adequately sets forth a claim upon which relief could be granted. *See Hatch*, 274 F.3d at 19; *Rodriguez-Ortiz*, 490 F.3d at 95. In Massachusetts, to prevail on a breach of contract claim, the Plaintiff, here Astellas, must show “1) there was an agreement between the parties; 2) the agreement was supported by consideration; 3) the plaintiff was ready, willing, and able to perform his or her part of the contract; 4) the defendant committed a breach of the contract; and 5) the plaintiff suffered harm as a result.” *Viken Detection Corp. v. Videray Techs. Inc.*, 384 F. Supp. 3d 168, 176 (D. Mass. 2019) (internal citations omitted). A contract need not be formalized, and email is sufficient. *See e.g. Shattuck v. Klotzbach*, No. 011109A, 2001 WL 1839720, at \*3 (Mass. Super. Dec. 11, 2001) (“[a] memorandum sufficient to satisfy the statute of frauds need not be a formal document”).

Astellas has adequately pled all of breach of contract elements here. The December 2011 emails set forth the agreement between the parties, with Astellas' Dr. Kimbrel establishing the terms and Defendants' Dr. Xu agreeing to said terms. (Ex. 3 to Sharkey Declaration, IMSTEM-0004606.) Defendants promised confidentiality and limitations to their use of Astellas' cells and information in exchange for the consideration of using Astellas' proprietary HB-MSC technology. *Id.* Astellas was ready, willing, and did in fact perform its part of the contract by providing said technology in the form of advice, protocols, and samples of frozen HB-MSC cells to Defendants. Defendants breached this contract, by improperly disclosing confidential information by filing a patent application on Astellas' technology and by using that technology as the basis for grant money, financial investment, and solicitation of venture capital in their own company, ImStem. Astellas was harmed by this breach by having spent its time, money, and effort on a deceptive collaboration, by having to bring this suit to avoid potentially being blocked from using its own technology by ImStem's [REDACTED] patent, and by the financial uncertainty arising from clouded intellectual property ownership rights.

Because this claim is sufficiently pled, the amendment is not futile and leave should be granted to allow Astellas to amend its pleading.

**C. Amendment Promotes Judicial Economy**

Judicial economy favors allowing the Court and/or a jury to resolve a breach of contract claim together with the other related tort claims. It is not an efficient use of the Court's time and resources to have a second litigation—and trial—on a nearly identical ImStem documents, the same operative facts, the same technical subject matter, and with substantively similar tort claim elements. As the Court recently agreed, “judicial economy may also be considered when deciding motions to amend.” (Dkt. 85 at 10 (*citing EMC Corp. v. Pure Storage, Inc.*, 310 F.R.D. 194, 202–03 (D. Mass. 2015); *Rockingham Cty. Nursing Home*, 2014 WL 176580, at \*9–10)). No one benefits from a second litigation regarding these communications, especially when addition of the claim has no impact on case discovery or deadlines.

**V. CONCLUSION**

Astellas respectfully requests that the Court allow it to add the new breach of contract count discussed above and included in its proposed Amended Complaint.

Dated: September 13, 2019

Respectfully submitted,

/s/ David P. Frazier

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**CERTIFICATE OF SERVICE**

I hereby certify that this document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing, and paper copies will be sent via first class mail on September 13, 2019 to those identified as non-registered participants.

/s/ David P. Frazier

David P. Frazier